C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

JAN - 5 2001

K003289
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BARD

SECTION VI

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name:	C. R. Bard, Inc., Medical Division
Address:	8195 Industrial Blvd. Covington, Georgia 30014
Contact Person:	Georgia C. Abernathy
Contact Person's Phone:	(770) 784-6454
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	September 28, 2000

B. Device Name:

Trade Name:	Bardex® Latex-Free Temperature-Sensing Foley Catheter (uncoated) Bardex® Lubri-Sil™ Temperature-Sensing Foley Catheter (lubricious-coated) Bardex® Lubri-Sil™ I. C. Temperature-Sensing Foley Catheter (silver/hydrogel-coated)
Common / Usual Name:	Temperature-sensing Foley catheter
Classification Name:	Urological catheter (uncoated and Lubri-Sil) Antimicrobial Urological Foley catheter (Lubri-Sil I. C.)

C. Predicate Device Name:

Trade Name:	Bardex® Temperature-Sensing Foley Catheter Bardex® Lubri-Sil™ Foley Catheter Bardex® Lubri-Sil™ I. C. Foley Catheter

D. Device Description:

The Bardex Silicone Temperature-Sensing Foley Catheter is a two-way silicone Foley catheter with a thermistor embedded in the third lumen. The catheters will be available uncoated, with a lubricious coating or with a silver and lubricious coating.

E. Intended Use:

The Bardex Silicone Temperature-Sensing Foley Catheter, when connected to a Bard CritiCore or Urotrack 224 Monitor, or other 400-Series Temperature Monitors, is intended for use in the

drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.

F. Technological Characteristics Summary:

Table VI-1 provides a tabulated comparison summary of the technological characteristics of the Bardex Silicone Temperature-Sensing Foley Catheters versus the predicate devices.

Table VI-1
Comparison Summary of Technological Characteristics

Component / Characteristic	Bardex Latex-Free Temperature-Sensing Foley Catheter (uncoated)	Bardex Lubri-Sil Temperature-Sensing Foley Catheter (lubricious coated)	Bardex Lubri-Sil I.C. Temperature-Sensing Foley Catheter (silver/hydrogel coated)	Bardex Latex Temperature-Sensing Foley Catheter (K834438) (predicate)	Bardex Lubri-Sil Foley Catheter (2-way) (K984084) (predicate)	Bardex Lubri-Sil I.C. Foley Catheter (2-way) (K984136) (predicate)
Indications or Intended Use	The Bardex Silicone Temperature-Sensing Foley Catheter, when connected to a Bard CritiCore or Urotrack 224 Monitor, or other 400-Series Temperature Monitors, is intended for use in the drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.	The Bardex Silicone Temperature-Sensing Foley Catheter, when connected to a Bard CritiCore or Urotrack 224 Monitor, or other 400-Series Temperature Monitors, is intended for use in the drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.	The Bardex Silicone Temperature-Sensing Foley Catheter, when connected to a Bard CritiCore or Urotrack 224 Monitor, or other 400-Series Temperature Monitors, is intended for use in the drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.	The device is intended to monitor localized body temperature, in degrees Fahrenheit and degrees Celsius, during the normal use of the Foley Catheter to provide early detection of infection at the site of the inserted device.	Intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract. Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.	Intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract. Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.

Component / Characteristic	Bardex Latex-Free Temperature-Sensing Foley Catheter (uncoated)	Bardex Lubri-Sil Temperature-Sensing Foley Catheter (lubricious coated)	Bardex Lubri-Sil I.C. Temperature-Sensing Foley Catheter (silver/hydrogel coated)	Bardex Latex Temperature-Sensing Foley Catheter (K834438) (predicate)	Bardex Lubri-Sil Foley Catheter (2-way) (K984084) (predicate)	Bardex Lubri-Sil I. C. Foley Catheter (2-way) (K984136) (predicate)
Design						
Catheter base material	Silicone	Silicone	Silicone	Latex	Silicone	Silicone
French sizes / Balloon sizes Available	8-10 Fr. / 3cc 12-18 Fr. / 5cc	8-10 Fr. / 3cc 12-18 Fr. / 5cc	8-10 Fr. / 3cc 12-18 Fr. / 5cc	* 14-18 Fr. / 5cc	8-10 Fr. / 3cc 12-24 Fr. / 5cc	12-24 Fr. / 5cc
Coating						
Coating	None	Hydrogel hydrophilic polymer	Silver and lubricious	None	Hydrogel hydrophilic polymer	Silver and lubricious
Catheter Surface Coated	None	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	None	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon

* For several years Bard has been marketing 8, 10 and 12 Fr. temperature-sensing silicone catheters which are manufactured by MRI. MRI holds a 510(k) for silicone temperature-sensing catheters.

G. Performance Data Summary:

The Bardex Silicone Temperature-Sensing. Foley Catheter referenced in this submission is held to the same design, manufacture, and performance specifications as those Foley catheters currently manufactured. Performance and functional testing standards are based on the FDA draft "Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters" dated September 12, 1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

Mr. Robert Mosenkis
President
C. R. Bard, Inc.
c/o Citech
5200 Butler Pike
PLYMOUTH MEETING PA 19462

Re: K003289
Bardex Latex-Free Temperature-Sensing Foley Catheter
Bardex Lubri-Sil Temperature-Sensing Foley Catheter
Bardex Lubri-Sil I.C. Temperature-Sensing Foley Catheter
Dated: October 19, 2000
Received: October 20, 2000
Regulatory Class: II
21 CFR §876.5130./Procodes: 78 EZL and MJC

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

SECTION I - D

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003289/S002

Device Name: Bardex Silicone Temperature-Sensing Foley Catheter

Indications for Use:

The Bardex Silicone Temperature-Sensing **Foley** Catheter, when connected to a Bard CritiCore or Urotrack 224 Monitor, or other 400-Series Temperature Monitors, is intended for use in the drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003289/S002